UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,253	09/17/1999	MICHAEL NEHLS	8535-026-999	9822

20583 7590 01/29/2002

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/398,253	NEHLS ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *03 January 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

4.☐ 3.☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1,3,4,10 and 11*.

Claim(s) withdrawn from consideration: *5-9*.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *Written Description Guideline example 7*

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Adams et al. (1997), in the Office Action mailed on July 2, 2001, is withdrawn in view of the arguments presented in the Amendment received on January 3, 2002he rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Adams et al. (1997), in the Office Action mailed on July 2, 2001, is withdrawn in view of the arguments presented in the Amendment received on January 3, 2002.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claims 1, 3, 4, 10, and 11 under 35 U.S.C. 101 as lacking patentable utility for the lacke of a specific, substantical, or credible utility, in the Office Action mailed on July 2, 2001 is maintained for the reasons of record. Applicants' arguments received on January 3, 2002 have been fully considered but they are not found persuasive. Applicants argue that the claimed polynucleotide are specific because the claimed polynucleotides were specific to the site of teratocarcinoma cells. Applicants also argue that the claimed nucleic acids have specific utility because they can be used to identify and study genes that are involved in the late stages of stem cell differentiation and development (pp. 4). Applicants then state that an understanding of molecular mechanisms which govern stem cell fate is therefore of fundamental significance in cell and developmental biology and the capabilities arising from such knowledge have major biomedical applications (pp. 4). These points are not found persuasive because although the claimed nucleic acids might be specific to the site of expression (or extraction), the claimed nucleic acids lack a substantial utility. Applicants arguments are drawn to the possible role of the claimed nucleic acids in developmental biology (which require further research of the claimed) without disclosing any immediate "real world," applicable, uses. Applicants arguments would only lead a skilled artisan to conduct further research on the claimed nucleic acids in the field of developmental biology. If this argument were to be taken, then all of the expressed sequences in bladder tumor, for example, would be patentable because they are specific to the site of expression (or extraction) and would be lead a skilled artisan to conduct further research on them. The utility guidelines require that the claimed subject matter have an immediate, real-world, applicability to satisfy the 101 utility. Also, Applicants are reminded that the Office Action mailed on July 2, 2001, gave only an example of what type of nucleic acids were considered to meet the utility requirements.
Finally, Applicants argue that the claimed nucleic acids have a substantial utility because the nucleic acids, "can be used as probes in hybridization assays well know in the art to determine the activity at the genetic loci during development and differentiation of the teratocarcinomas (pp.5). This argument is not found persuasive because a skilled artisan would not know how to apply the results of the hybridization of the claimed nucleic acid (other than to conduct further research) for a real-world application (i.e., if a nucleic acid 'a' is expressed more, what does it mean?).

For the reasons above, Applicants arguments are not found to be persuasive and the rejection under 35 U.S.C. 101 is maintained.

The rejection of claims 1, 3, 4, 10, and 11 under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, in the Office Action mailed on July 2, 2001 is maintained for the reasons of record. Applicants' arguments received on January 3, 2002 have been fully considered but they are not found persuasive for the reasons already set forth above.

The rejection of claims 1, 3, 4, 10, and 11 under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the Office Action mailed on July 2, 2001 is maintained for the reasons of record. Applicants' arguments received on January 3, 2002 have been fully considered but they are not found persuasive.

Applicants argue that the isolated polynucleotides or oligonucleotides corresponding to one of the elected SEQ ID Numbers are fully described by structure or by physical properties because claim 1 recites synthetic oligonucleotides that comprise a contiguous stretch of at least about 15 nucleotides and one skilled in the art would be able to make the synthetic oligonucleotides as described in claim 1. This point is not found persuasive because the specification did not disclose the full open reading frame from which the oligonucleotides are derived. Absent this disclosure in the specification, the claimed polynucleotides or synthetic oligonucleotides read on a full-length cDNA which are not described (See attached Written Description guideline example 7).

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER

Example 7: EST

Specification: The specification discloses SEQ ID NO: 16 which is a partial cDNA. The specification does not address whether the cDNA crosses an exon/intron splice junction. The specification discloses that this sequence will specifically hybridize with the complement of the coding sequence of a gene of an infectious yeast. The presence of the nucleic acid detected by hybridization with the complement of the coding sequence is useful for identifying yeast infections. Example 1 of the specification describes an experiment where SEQ ID NO: 16 was determined following characterization of a cDNA clone isolated from a cDNA library.

Claim:

An isolated DNA comprising SEQ ID NO: 16.

Analysis:

A review of the full content of the specification indicates SEQ ID NO: 16 is essential to the operation and function of the claimed invention. The specification indicates that the presence of DNA that hybridizes with SEQ ID NO: 16 is indicative of a yeast infection.

A review of the language of the claim indicates that the claim is drawn to a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 16 within it including any full length gene which contains the sequence, any fusion constructs or cDNAs.

The search indicates that SEQ ID NO: 16 is a novel and unobvious sequence.

There is a single species explicitly disclosed (a molecule consisting of SEQ ID NO: 16 that is within the scope of the claimed genus).

There is actual reduction to practice of the disclosed species.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 16 is only a fragment of any full-length gene or cDNA species. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "A cDNA comprising [a partial sequence]," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. Further, defining "the" cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a

substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., SEQ ID NO: 16. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO: 16 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 16, 2) the breadth of the claim as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 16.

Conclusion: The written description requirement is not satisfied.

Caveat: *In situations where the specification indicates that the SEQ ID NO: is a full-length cDNA open reading frame and the claim* ***cannot*** *read on a gene, the claimed invention would meet the written description requirement.*